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PURPOSE

The Federal Controlled Substances Act and federal regulations establish important laws and regulations governing the purchase, receipt, storage, and dispensing of controlled substances. This policy outlines the processes and procedures which must be followed in order to comply with federal law, in regards to all controlled substance related activity.

SCOPE

This policy and procedure applies to all CVS Pharmacy® Retail Stores.

POLICY

GENERAL REQUIREMENTS

Controlled substances are drugs that have a high potential for addiction and abuse. As a result, the manufacturing, possession, and/or use of controlled substances are strictly regulated by federal and state governments. All CVS Health® colleagues are responsible for compliance with federal and state controlled substances laws and regulations. All colleagues involved in ordering, receiving, storing, dispensing, or otherwise disposing of controlled substances will receive ongoing training on controlled substances procedures.

PROCEDURES

1. RECORD KEEPING

Every Pharmacy must maintain complete and accurate records that comply with all applicable laws and regulations governing the content, manner, and period of retention for controlled substance records.

- Schedule II controlled substance prescriptions and records must be separated from Schedule III-V controlled substance prescriptions and records
- All Schedule III-V controlled substance prescriptions and records must be separated from all non-scheduled drug prescriptions
- Controlled substance records must be kept separate from all other records and be readily retrievable
- All prescriptions must be filed in numerical order
- Federal law requires that a Pharmacy keep controlled substance **records on-site in the Pharmacy for two (2) years; however CVS Pharmacy has an internal record retention**

policy where records are required to be retained for longer. The records greater than two (2) years old must be retrievable but may not be required to be on-site, depending on state rules. The records retention schedule can be viewed by clicking the link at the bottom of this section. The following records are to be stored in the Pharmacy's Regulatory Records Box (note, this is not a list of folders within the box):

- Executed DEA 222 forms (or the electronic equivalent)
- POA authorizations and licenses
- Receipts and/or invoices for schedules II, III, IV, and V controlled substances
- Controlled substance inventory records, including the Initial, Annual, Biennial, Newly Scheduled Controlled Substance, Change of Pharmacy Manager, and Acquired Inventory
- Controlled substance and PSE distribution records (i.e., sales to other registrants, returns to vendors, distributions to Reverse Distributors)
- Initial Notifications and DEA 106 forms
- Records of transfers of controlled substances between pharmacies (e.g. acquired inventory)
- DEA registration certificate (if not required to be posted in your state)
- PSE Manifests
- Other State Required Records (ex: DHEC, DPS, BNDD, BOP Self-Inspection or BOP Self-Audit)
- Offsite Record Storage Documents (Iron Mountain)
- Miscellaneous (ex: BOP/DEA waiver requests to store records offsite, BOP remodel applications, etc.)

- Pharmacies that are registered DEA "collectors" participating in the CVS Pharmacy In-Store Medication Disposal Program are also required to maintain a "step log" documenting the inner liners in their possession, as well as the annual inventory of the inner liners
  - **Reference:** In-Store Medication Disposal Program
- **Some state regulations are more stringent than federal regulations; in these cases the state requirement must be followed**
  - It is the responsibility of all Pharmacy colleagues, and particularly the Pharmacy Manager, to be aware of the applicable state recordkeeping requirements
  - If you have any questions regarding state recordkeeping requirements, you may send your question to Pharmacy Operations
  - **References:**
    - Document Retention and Confidential Pharmacy Records Retention and Storage
    - Target Channel: Document Retention and Confidential Pharmacy Records Retention and Storage

2. DEA 222 FORM INFORMATION

DEA 222 forms are issued in multiples of seven or fourteen and sequentially numbered. When the forms are received, they must be counted and the order form serial numbers must be verified.

- Order forms cannot be used unless they contain the correct Pharmacy name, address, and registration number, this information must also be verified upon receipt of the DEA 222 forms:
  - Forms that cannot be used because of a change in the name or location of the Pharmacy must be returned to the DEA regional office
  - If your store receives DEA 222 forms that do not reflect your store's correct information, such as the address and DEA number, the order forms may not be used. The local DEA office must be notified of the incorrect forms, and the forms returned to avoid accidental use
- Unexecuted order forms must be stored in the Schedule II safe to prevent loss or theft
- Form 222a is used to requisition additional DEA Forms 222. This form can be found at:
  - https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp
- DEA 222 forms must be executed in the sequential order of their serial numbers. Forms must be legibly completed (no cross-outs or write-over's) since suppliers are not permitted by law to fill orders submitted on illegible or altered order forms
  - **Reference:** Ordering and Receiving CII Drugs on the DEA 222 Form
- Lost or stolen DEA Forms 222 must be reported to the local DEA Diversion Field office. The Pharmacist must also immediately notify the Field Leader and District Asset Protection Leader
  - When reporting the theft or loss of a DEA 222 form, the Pharmacist must include the serial numbers of each lost or stolen order form
- If an order form is lost in transit after it has been executed and sent to the wholesaler or manufacturer (e.g., order form lost in the mail en route to the wholesaler or manufacturer), a new order form is required. DEA does NOT need to be notified
  - The Pharmacist must complete a second order form so the supplier can fill the original order
  - The Pharmacist must attach a statement to the new order form that contains the following information:
    - The serial number of the lost order form
    - The date on the lost form
    - A statement that the drugs were never received
  - Make two copies of the lost order form statement.
    - Attach the original to copy 3 (the retained copy) of the lost order form
    - Attach one copy to the replacement order form copies 1and 2 when sent to the wholesaler or manufacturer
    - Executed DEA 222 Forms must be kept with the Schedule II invoices and stored in the Regulatory Records box
  - **Reference:** Pharmacist on Duty DEA 222 Loss Reporting Job Aid

3. ORDERING SCHEDULE II CONTROLLED SUBSTANCES

- Only the Pharmacist(s) who have Power of Attorney are authorized to place orders for Schedule II controlled substances
  - **Reference:** Pharmacists in Charge and Powers of Attorney at CVS Pharmacy Retail Stores – **Power of Attorney section**

- If a Pharmacist with Power of Attorney is not available to sign the DEA 222 form, the store may not order Schedule II drugs
  - DEA 222 order forms must be signed at the time the order is being created. In no instance should order forms be pre-signed by the Power of Attorney Pharmacist for future use
- All federal Schedule II controlled substances must be purchased using the DEA Form 222. If the state you are located in also requires an order form for a state Schedule II controlled substances, a DEA 222 form may be used
  - DEA 222 forms must contain the correct Pharmacy name, address, and registration number
  - **Reference:** Ordering and Receiving CII Drugs on the DEA 222 form

4. RECEIVING SCHEDULE II CONTROLLED SUBSTANCES

Upon receipt of Schedule II controlled substances, a Pharmacist must physically count all items received while the delivery driver is present. If the full amount of the controlled substances reflected on the invoice is not received in the order, the Pharmacist MUST refuse the entire order and send it back to the wholesaler.

- If the full amount of controlled substances reflected on the invoice are contained in the order being received, the Pharmacist is required to conduct the following actions on the retained copy (copy 3) of the DEA 222 form:
  - Enter the amount received (No. of Packages) for each item listed on each line of the DEA 222 form
  - Date each line for each item received on the DEA 222 form
  - Sign the DEA 222 form
  - Do not use ditto marks or arrows
  - A quantity of zero and date is still required when no product is received
- In addition, all Schedule II products (whether federally or state scheduled) must be checked into the electronic perpetual inventory by the Pharmacist immediately upon receiving delivery
  - Only Pharmacists are allowed to handle Schedule II medications
- If a discrepancy exists between the amount received and the invoice quantity, the discrepancy must be investigated immediately
  - **Reference:** Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals
  - **Reference:** Ordering and Receiving CII Drugs on the DEA 222 form
  - A separate file of invoices and executed DEA 222 forms for Schedule II controlled substances must be maintained in the Regulatory Records box as required by the CVS Pharmacy Document Retention Schedule
    - **References:**
      - Document Retention and Confidential Pharmacy Records Retention and Storage
      - Target Channel: Document Retention and Confidential Pharmacy Records Retention and Storage

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5. ORDERING SCHEDULE III – V CONTROLLED SUBSTANCES

- Ordering Schedule III, IV, and V controlled substances must occur in accordance with non-scheduled medication purchasing procedures per your state regulations
    - If an order is deemed to be suspicious after the due diligence process is completed, the SOM team will cancel the order of the suspicious drug family for the store in question
    - All future Distribution Center orders will automatically be blocked until all remediation plans are implemented
    - Field Leaders will be notified that they are to instruct the store who placed the order not to place future orders to the Outside Vendor until all remediation plans are implemented
        - **Reference:** Controlled Substance & DEA List 1 Chemical Order Monitoring Process

6. RECEIVING SCHEDULE III-V CONTROLLED SUBSTANCES

- Upon receipt of Schedule III-V substances all medications must be checked in piece by piece against the invoice by the Pharmacist/Pharmacy Technician
- Each invoice (both CVS Pharmacy warehouse shipments and Outside Vendor shipments), must contain the following elements:
    - Symbol to show receipt of each quantity of product received
    - The date of receipt must be handwritten or stamped on the invoice
    - The Pharmacist's and/or Technician's signature to signify that the amount listed on the invoice was received in the Pharmacy
- The invoice must then be kept in the Regulatory Records box. The Schedule III-V invoices must be kept separately from the Schedule II invoices in the proper folders
- When receiving an Outside Vendor order, if there is an apparent discrepancy between the invoice and the order at the time of delivery and while the driver is still in the store, the Pharmacy must refuse the entire order and return it to the Outside Vendor. If the discrepancy is identified after the driver has left and while the order is being checked in, the Outside Vendor should be notified and the discrepancy should be handled through the standard loss reporting process
- If there is a discrepancy with a Distribution Center (warehouse) order, call Distribution Services at 401-770-5555
- Any discrepancies between the amount received and the invoice quantity must be investigated immediately. Resolutions must be documented
    - **Reference:** Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals
- The order must be stored immediately in the designated areas of the Pharmacy including Pharmacy shelves, cabinets, Schedule II safe, or refrigerator
- Schedule III-V controlled substances must be kept dispersed throughout the non-controlled inventory in a limited-access area of the Pharmacy, except as outlined in Section 7

- **Reference:** Pharmacy Warehouse Delivery – **Checking In Warehouse Deliveries section**

7. STORAGE AND SECURITY OF CONTROLLED SUBSTANCES

- After receipt and confirmation of the amount received, the controlled substances must be stored immediately in the designated areas of the Pharmacy to include shelves, cabinets, Schedule II safe, or refrigerator
  - Schedule II controlled substances must be stored in the securely locked designated Schedule II safe, except as allowed by CVS Pharmacy policy Shoplifting/Robbery/Burglary . Only registered Pharmacists may have access to the Schedule II safe. The Schedule II safe must be kept locked
    - Items other than Schedule II medication and unused DEA 222 forms are not to be kept in the Schedule II safe or Narcotic cabinet. Schedule III-V medications may be stored in the Schedule II safe only at the recommendation and approval of Loss Prevention or your Pharmacy Supervisor or as stated as a security measure from a submitted DEA 106 form
    - In the event Schedule III-V medications are approved to be stored in the Schedule II safe, the same security measures as for Schedule II must be taken for all contents; only Pharmacists are permitted to have access to the medications in the Schedule II safe
    - Under no circumstances are non-controlled medications to be kept in the Schedule II safe or narcotic cabinet
  - Schedule III, IV, and V controlled substances must be dispersed throughout the non-controlled inventory in a limited-access area of the Pharmacy
- The Pharmacy Manager must comply with all storage requirements of their State Board of Pharmacy
- Only registered Pharmacists may have keys, combinations or codes, to Schedule II safes, refrigerators, cabinets, or alarms where controlled substances are located
- Each Pharmacist while on duty shall be responsible for the security of all drugs held within the Pharmacy
- Every Pharmacy must have an alarm system that is designed to provide coverage to all areas where all medications including controlled substances are stored when the Pharmacy is closed
  - **References:**
    - Pharmacy Access and Security
    - Store in Store - Pharmacy Access and Security

8. DEA REQUIRED INVENTORIES AND DOCUMENTATION

Federal law requires all Pharmacies to complete a biennial controlled substance inventory; however, many states have more stringent regulations that require controlled substance inventories and company policy is that complete controlled substance inventories be completed on an annual basis. Additionally, Field Leaders must ensure a controlled substance inventory is

performed for any changes in Pharmacy Manager or change of ownership due to an acquisition, or acquisition of inventory in a file-buy or store-buy.

- Annual inventories must be completed on the same date each year either after closing on April 30th or before opening on May 1st, unless your state has different requirements or if the Pharmacy Operations Team instructs otherwise
- The change of Pharmacy Manager inventory must occur prior to the start of dispensing by the new Pharmacy Manager
- The inventory procedures for the acquisition of controlled drugs from a file-buy or store buy must follow documented policy
    - **Reference:** Inventory, Control Drug Transfer, and Store License Procedures for File Buy Acquisitions
- In a 24 hour store, inventories must be completed during the overnight hours between midnight and 6am on May 1st
- There must not be any dispensing of controlled substances while the inventory is being completed
- All newly licensed pharmacies and newly assigned Pharmacy Managers must complete an initial inventory of all controlled substances
- An annual inventory of all controlled substances is required, or more frequently as required by state law
- All inventories must contain the following information:
    - Type of inventory (Annual, or Change of Pharmacy Manager)
    - The name, address, and DEA registration number of the Pharmacy
    - The date and time of the inventory (open or close the business day)
    - The inventory must separate out Schedule II drugs from Schedule III-V drugs
    - The names of all controlled substances
    - The dosage form and unit strength of each controlled substance
    - The number of units or volume in each container of controlled substances
    - The number of commercial containers of each controlled substances
    - Pharmacies that are registered DEA "collectors" participating in the CVS Pharmacy In-Store Medication Disposal Program are also required to include in their inventories an accounting of the inner liners in their possession
        - **Reference:** In-Store Medication Disposal Program
    - If no controlled substances are on hand at the time of the inventory, the Pharmacist must record an inventory stating that no controlled substances are in inventory
        - Some states require PSE, butalbital products, and/or Drugs of Concern products to be included in the inventory. Refer to RxNet to access the state specific requirements

The Pharmacy Manager is responsible for the accurate and timely completion of all required controlled substance inventories:

- Refer to RxNet to view your **state specific requirements** and device process steps for the annual controlled substance inventory

- The complete inventory and attached cover sheet must be stored in the Regulatory Records Box
  - As required by federal regulations, inventories must be retained on-site and readily retrievable for a minimum of two (2) years, unless longer retention is required by the state
  - Schedule II controlled substance inventories must be maintained separately from Schedule III-V controlled substance inventories
    - Each inventory must have its own coversheet with the required information in order to be compliant
    - Inventories must include all state and federally scheduled drugs on hand at the time each inventory is conducted. This includes controlled substances in the waiting bin, refrigerators and freezers, in quarantine, and awaiting return to non-saleable returns vendor(s)
  - Each controlled substance inventory must be maintained separate from all non-scheduled medication documentation
  - **Reference:** Controlled Substance Inventory

9. PERPETUAL AND MONTHLY INVENTORY REQUIREMENTS AND DOCUMENTATION

9.1 PERPETUAL:

- Every transaction, including receipt, dispensing, and returns, involving a Schedule II controlled substance will be recorded in the electronic perpetual inventory
- All waste and outdated controlled substances awaiting destruction must be included in the electronic perpetual inventory
- In the event that a manual perpetual inventory must be maintained, the Pharmacist will record all incoming and outgoing product on the appropriate paper Perpetual Inventory Log
  - **Reference:** Controlled Substance Perpetual Inventory Resource Center
    - Refer to the Store Supply Guide on RxNet to obtain the item number
    - Retain any paper perpetual inventory logs on-site as required by the CVS Pharmacy Document Retention Schedule
      - **References:**
        - Document Retention and Confidential Pharmacy Records Retention and Storage
        - Target Channel: Document Retention and Confidential Pharmacy Records Retention and Storage
- Any discrepancies must be investigated immediately. If controlled substances cannot be accounted for, follow the loss/theft reporting process
  - **Reference:** Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals

9.2 MONTHLY INVENTORIES:

- A complete count of all Schedule II drugs will be performed at least every 30 days and recorded in the perpetual inventory (or more frequently, if required by your state)
- All counts prompted by the electronic perpetual inventory must be completed by the due date/time indicated
- At the discretion of the Pharmacy Manager, Field Management, or as required by state law inventories may be conducted more frequently
- Any discrepancies must be investigated immediately. If controlled substances cannot be accounted for, follow the loss/theft reporting process
    - **Reference:** Reporting Theft or Loss of Controlled Substances/PSE/E Listed Chemicals

10. THEFT OR LOSS REPORTING PROCEDURE

Click to view the policy from the Policy and Procedure Page on RxNet: Reporting Theft or Loss of Controlled Substances/PSE/E Listed Chemicals

- If you have any questions regarding theft/loss reporting, you may send your question to Drug_Loss_Program@CVSCaremark.com

11. LOST IN TRANSIT (In-Transit Losses)

Click to view the policy from the Policy and Procedure Page on RxNet: Reporting Theft or Loss of Controlled Substances/PSE/E Listed Chemicals - In-Transit Losses section

- If you have any questions regarding theft/loss reporting, you may send your question to Drug_Loss_Program@CVSCaremark.com

Shipping from the Pharmacy to a Reverse Distributor:

- If a shipment of controlled substances is lost in transit from the Pharmacy to an authorized Reverse Distributor and the Pharmacy is notified by UPS or the Reverse Distributor of the loss, the Field Leader and District Asset Protection Leader must be notified immediately so that an investigation can be launched
- The Pharmacy (as the supplier) is responsible for filing an Initial Notification within 24 hours unless the Reverse Distributor signed for the delivery
- If the Reverse Distributor signed for the delivery, then the Reverse Distributor is responsible for notifying DEA. However, CVS Health shall cooperate with the investigation being performed by the Reverse Distributor
    - **Reference:** Schedule II Non-Saleable Returns

12. SCHEDULE III – V RETURNS

- When the Pharmacy is returning Scheduled III-V controlled substances to a Reverse Distributor the Pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred
- FedEx Supply Chain (formerly Genco)
    - A non-saleable return must be completed at least once per month by the 10th of every month to the Reverse Distributor that contains:

- Schedule III-V items in an original manufacturer's container (stock bottle, tube of cream, box of patches, insulin vial, etc.) except if it is leaking or a reconstitute that has already been mixed within the 1x1 window
- Schedule III-V recalled items (original manufacturer's container and amber vials)

- A non-saleable return is completed using the handheld RF Unit or CFRx application
- For each product being returned:
  - The UPC barcode is scanned (or NDC keyed manually)
  - Product expiration date is entered
- Once all Schedule III-V items to be returned are scanned, the in-progress key rec must be reviewed prior to completion. Screen Print or review Non-Saleable Return details on the terminal prior to completing the key rec
- Count all controlled substances (Schedule III-V) within the Rx Returns box to confirm that all controlled substances are accurately listed on the in-progress key rec
- Once completed, two (2) copies of the key rec will print on the Pharmacy printer
- The Pharmacist on duty must audit every Rx Genco Schedule III-V Detail Report key rec for accuracy
  - Use a verification symbol (e.g., checkmark, circle, slash, etc.) to confirm validation of the total quantity of each controlled substance in the return and on the key rec, then sign and date the completed controlled substance key rec
  - Signing the key rec is confirmation that the controlled substance return information on the key rec matches the contents of the return
    - Three (3) requirements for documentation of non-saleable Schedule III-V returns:
      - Verification symbol (e.g. checkmark, circle, slash, etc.) validating total quantity of each drug contained in the return
      - Pharmacist Signature
      - Date
- Place all non-Schedule II medications in the Rx Returns cardboard box (box can be ordered via Store Supplies with the warehouse delivery)
  - Seal each box securely with clear packing tape along both the top and bottom seams
  - Place a note with the key rec number in the label pouch to assist with placing the correct UPS label on the box
- The UPS label will be available in the online system 24 to 48 business hours after processing the key rec
  - Print two copies of the UPS label from the online system (or immediately photocopy the printed label)
  - Affix the original UPS shipping label to the correct cardboard box immediately after it has been printed from the online system

- Each label is specific to one key rec. Labels from other processed returns cannot be affixed to other returns
- Hand all prepared boxes to the UPS driver at the next UPS visit
- Keep one copy of each key rec for your records:
  - The notated and signed Schedule III-V Detail Report must be placed in the Regulatory Records Box
  - Attach a copy of the UPS label to the matching signed key rec in the Regulatory Records Box
- Retain all copies of invoices. Refer to the following policies for paperwork retention guidelines:
  - Document Retention and Confidential Pharmacy Records Retention and Storage
  - Target Channel: Document Retention and Confidential Pharmacy Records Retention and Storage

- StrongPak
  - A key rec must be completed at least once every week by Thursday of each week that contains:
    - Schedule III-V **amber vials** except recalled items (within the 1x1 window)
    - Schedule III-V loose pills except recalled items
    - Schedule III-V **compounded prescription items** (within the 1x1 window)
    - Schedule III-V **leaking OR reconstituted items** which have already been mixed in original manufacturer's container
  - A key rec is completed using the handheld RF Unit or CFRx application
    - For each product being returned:
      - The UPC barcode is scanned (or NDC keyed manually)
      - Product expiration date is entered
  - Once all Schedule III-V items to be processed from the Akrobin are scanned, the in-progress key rec must be reviewed prior to completion. Screen Print or review Non-Saleable Return details on the terminal prior to completing the key rec
  - Count all controlled substances (Schedule III-V) within the StrongPak self-sealing bag to confirm that all controlled substances are accurately listed on the in-progress key rec
  - Once completed, two (2) copies of the key rec will print on the Pharmacy printer
  - The Pharmacist on duty must audit every StrongPak Controlled key rec for accuracy
    - Use a verification symbol (e.g., checkmark, circle, slash, etc.) to confirm validation of the total quantity of each controlled substance in the return and on the key rec, then sign and date the completed controlled substance key rec
    - Signing the key rec is confirmation that the controlled substance return information on the key rec matches the contents of the return
      - Three requirements for documentation of non-saleable StrongPak controlled substance returns:

- Verification symbol (e.g. checkmark, circle, slash, etc.) validating total quantity of each drug contained in the return
- Pharmacist Signature
- Date

- All scanned inventory waste items are placed in a "weekly bag" after the key rec is audited
- Schedule III-V items must be placed in a separate "weekly bag"
- The "weekly bag" will not be complete without the Pharmacist's signature on the key rec
- Place one copy of the key rec in the "weekly bag" and keep one copy for your store's records
- Place each "weekly bag" in the hazardous waste tote
- Keep one copy of each key rec for your records:
  - The notated and signed StrongPak controlled key rec must be placed in the Regulatory Records box
    - All shipments including pick-ups involving controlled substances by Stericycle must include the required DEA information which is contained on the Product Transfer Schedule (PTS) provided by StrongPak personnel during pick-up of the controlled substance
    - Should any PTS documentation not be provided during pick-up or if any PTS documentation is lost, PTS reports can be viewed and printed on the Environmental Health and Safety Reports link via Radar
  - The PTS must be reviewed and signed by the Pharmacist, at the time of pick up and attached to the StrongPak Controlled Substance Key Rec and retained in the Schedule III-V Return/Destruction folder in the Regulatory Records box
- Retain all copies of invoices. Refer to the following policies for paperwork retention guidelines:
  - Document Retention and Confidential Pharmacy Records Retention and Storage
  - Target Channel- Document Retention and Confidential Pharmacy Records Retention and Storage
- **Reference:** Program Support Page titled Non-Saleable Returns on RxNet

13. SCHEDULE II RETURNS

Click to view the policy from the Pharmacy Operations Policy and Procedures Page: Schedule II Non-Saleable Returns.

- **Reference:** Program Support Page titled Non-Saleable Returns on RxNet

14. DISPENSING CONTROLLED SUBSTANCES

All dispensing of controlled substances must comply with federal and state laws and regulations.

- CVS Pharmacy Pharmacists must not perform data entry, produce, or verify controlled substance prescriptions written by a Prescriber for themselves (the Pharmacist) or family member living within the same household
- CVS Pharmacy Pharmacists must not fill controlled substance prescriptions that are written by a Prescriber for themselves (the Prescriber) or for their family members
- CVS Pharmacy Technicians or Interns are not permitted to perform Data Entry, Production or POS activities on controlled substance prescriptions that have been issued for themselves (the Technician or Intern) or family members
    - Family members are defined as a spouse, parent, child, sibling or other individual in relation to whom a Pharmacist/Prescriber's personal or emotional involvement may render that Physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions
- CVS Pharmacy Pharmacists must not fill controlled substance prescriptions where the Prescriber wishes to use the prescription to supply the Prescriber with an inventory of drugs that the Prescriber intends to administer/dispense to patients. Such prescriptions may appear to be written for the Prescriber themselves, for their "office use," for a "doctor bag" or other similar patient designation
- CVS Pharmacy requires that all scheduled medications be dispensed pursuant to a valid prescription. Over-the-counter sale of any quantity of such product is prohibited, even if allowed by law. This includes but is not limited to codeine-containing preparations (e.g. Cheratussin AC, Robitussin AC) and Paregoric. This does not apply to the sale of pseudoephedrine products in states where PSE is a controlled substance. For PSE sales, refer to policy OTC Pseudoephedrine (PSE)

14.1 CORRESPONDING RESPONSIBILITY

DEA regulations require that a controlled substance prescription must be issued for a **legitimate medical purpose** by an individual Practitioner, acting in the usual course of his/her medical practice.

- The initial responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing Practitioner; however DEA regulations place **"corresponding responsibility"** on the Pharmacist who fills the prescription
- **Reference:** Guidelines for Dispensing Controlled Substances

14.2 CONTACTING PRESCRIBERS FOR CLARIFICATION

A controlled substance prescription is considered valid as long as both of the following requirements have been met.

- The prescription must have been issued for a legitimate medical purpose by a Prescriber, acting in the usual course of his or her professional practice
- It contains all the federal and applicable state requirements for a controlled substance prescription

If the Pharmacist has a question about a prescription, the Pharmacist **must** contact the Prescriber for clarification and verification before filling the prescription.

- Where the Prescriber is not familiar to the Pharmacist, the Pharmacist must attempt to independently locate the Prescriber's contact information before resorting to any phone number listed on the prescription
- Conversation with the Prescriber's office must be documented on the actual prescription and in RxConnect
    - For prescription clarifications, such as missing patient, Prescriber, or drug information, the information must be written legibly on the hardcopy prescription. Additionally, the name of the person spoken to at the Prescriber's office must be documented along with the date and time that the conversation occurred
    - For clinical questions concerning the patient and/or prescription, the information must either be documented on the hardcopy prescription or in RxConnect by utilizing the patient notes functionality
    - **Reference:** Accepting Prescriptions

Even if a Prescriber indicates that the prescription should be filled as written, the Pharmacist must use his/her professional judgment to determine whether the prescription was issued for a legitimate medical purpose in the normal course of professional practice.

- Pharmacists must access and review PMP data, if available in your state, whenever they identify red flags that are not able to be resolved or are reasonably certain that a person may be attempting to obtain a Schedule II-V controlled substance for fraudulent, illegal, or a medically inappropriate purpose. This review will provide a more complete controlled substance history to use their professional judgment and base their decision on whether to fill or refuse to fill that prescription.
    - If a state requires mandatory PMP checks, the Pharmacist on duty must comply with the State's requirements
    - **Reference:** Prescription Drug Monitoring Program

14.3 RED FLAGS

The following are non-exclusive lists of some of the patient and Prescriber red flags to consider when exercising your corresponding responsibility:

PATIENT RED FLAGS

- **Distance**
    - Either or both the patient and Prescriber not being located within the Store's geographic area (in most cases)
    - Patient traveling distances to Pharmacy or Doctor
- **Cash**
    - Cash payment for prescriptions, particularly if RxConnect indicates the patient has insurance
- **Suspicious Behavior**
    - Customers arriving in groups to get narcotic prescriptions filled
    - Customer requests specific drugs by brand name or description (e.g., M's, blues, Mallinckrodt blues)
    - Customer appears to be visibly impaired, intoxicated or incoherent
- **Early Fills**

  - Customer attempting refill early or consistently showing up at the first available moment when refill can be obtained under standard practice
- **Doctor Shopping**
  - Evidence of multiple Prescribers s issuing controlled prescriptions for customer after review of profile or PMP data
- **Appropriateness of Therapy**
  - Patient remains on long-term high dose opioid long after injury has healed

PRESCRIBER RED FLAGS

- **Professional Practice**
  - Prescribes the same medication in the same dosage amount to most or all of their patients
  - Use of preprinted or stamped prescriptions
- **Cocktails**
  - Routinely prescribes the same combination of pain drugs for most or all of their patients
  - Prescribes combinations the DEA has identified as having a high potential for abuse (e.g., oxycodone, alprazolam and carisoprodol)
- **Scope of Practice**
  - Prescribing of narcotics does not fit with the Prescriber's practice (e.g., ophthalmologist)
- **Appropriateness of Therapy**
  - Overprescribing large doses of controlled substances to patients

15. ACCEPTING SCHEDULE II PRESCRIPTIONS

If the prescription was written for a legitimate medical purpose, it must contain all required information including:

- Patient's full name and address
- Drug name, strength, dosage form and quantity
- Directions for use
- Prescriber's full name, address, and DEA registration number
  - When entering prescription information into RxConnect, all Pharmacy colleagues must ensure that correct Prescriber information is entered. There can be multiple Prescribers with similar names and you must make sure that the correct Prescriber is identified and selected
- Manual signature of the Prescriber or signature of the Prescriber for EPCS (is an electronic file our system checks for)
- **Reference:** Accepting Prescriptions

15.1 FAXED SCHEDULE II PRESCRIPTION

Faxed Schedule II prescriptions may be filled and prepared; however, they are not to be dispensed until the Pharmacy receives the original, hard copy prescription.

Faxes can be accepted if the prescription is for a resident of a long term care facility or patients of a Medicare/state-licensed hospice. If for a hospice patient, the faxed prescription must contain a notation to that effect. Be aware that certain states require additional notations on faxed prescriptions.

- **Reference:** Controlled Substance Prescriptions for Hospice Patients

Due to the requirement that faxed prescriptions for controlled substances have been originally wet-signed, controlled substance prescriptions received from electronic fax applications where the signature is affixed within the application (e.g., Doximity, RingCentral) are not valid.

15.2 ORAL SCHEDULE II PRESCRIPTION

While emergency prescriptions should be an extremely rare occurrence, federal law permits an emergency Schedule II prescription to be phoned into the Pharmacy. **CVS Pharmacy limits the amount of an emergency telephone Schedule II prescription to a seventy-two (72) hour supply.**

The Prescriber must follow up with a written prescription within **seven (7) days** unless state law is more restrictive; Pharmacists are responsible for knowing their state's particular requirements. The hardcopy prescription must have written on its face "Authorization for Emergency Dispensing," and the date of the oral order.

If the Pharmacy does not receive the written prescription from the Prescriber within seven (7) days, the Pharmacy Team must notify the local DEA office. Some states will have specific forms that are to be used for the notification and may require that state entities also be informed.

The Pharmacist must follow all RxConnect prompting relative to hardcopy receipt following dispensing an emergency telephone Schedule II prescription. This includes confirming receipt of the required hardcopy prescription, and prescriber and/or DEA outreach at the appropriate time in the event the required hardcopy prescription is not received. When prompted, the Pharmacist on duty must credential to confirm the required action has been completed.

Oral prescriptions for **controlled substances (Schedules II, III, IV, and V)** may only be accepted by a Licensed Pharmacist, Graduate Intern , or registered Undergraduate Interns (where allowed).

- **Reference:** Accepting Prescriptions

15.3 PARTIAL FILL OF SCHEDULE II PRESCRIPTION

A partial fill for Schedule II is allowed if a Pharmacist cannot supply the full quantity written, provided that the Pharmacist notes the quantity on the prescription and the remaining portion is dispensed within seventy-two (72) hours.

- If the remaining portion cannot be dispensed within the seventy-two (72) hour period, the Pharmacist must notify the Prescriber and get a new hard copy prescription

- A single Schedule II hardcopy prescription CANNOT be split into two separate prescriptions (i.e. Oxycontin 15mg #180 into Oxycontin 15mg #120 and Oxycontin 15mg #60) due to insurance limitations or patient request to only bill a certain quantity
- If the Prescriber writes two separate hard copies to accommodate an insurance limitation, ensure the patient is not part of a "locked-in" state program. The requirements of "locked-in" programs require all scripts must be billed to the holder's insurance and rejections must be dealt with by calling the agency, not by processing to cash or cash discount
- The only instance allowing a partial fill would be in the rare occurrence that there is an out-of-stock situation requiring an Outside Vendor order to complete fulfillment

15.4 REFILLS OF SCHEDULE II PRESCRIPTION

Schedule II prescriptions may **not** be refilled. However, in some cases, DEA regulations allow Practitioners to write multiple prescriptions for Schedule II drugs to be dispensed over a number of months:

- The total amount prescribed and dispensed pursuant to all of the prescriptions must be limited to a 90 day supply
- Each prescription must be issued on a separate prescription blank
- Each separate prescription must be issued for a legitimate medical purpose by an individual Practitioner acting in the usual course of professional practice
- The Practitioner must provide written instructions on each prescription **indicating the earliest date the Pharmacy may fill the prescription**

Note that some states do not permit multiple prescriptions for Schedule II drugs.

16. ACCEPTING SCHEDULE III-V PRESCRIPTIONS

A Schedule III-V prescription must contain all required information including:

- Patient's full name and address
- Drug name, strength, dosage form, and quantity
- Directions for use
- Number of authorized refills, if any
- Prescriber's full name, address, and DEA registration number
  - When entering prescription information into RxConnect, all Pharmacy colleagues must ensure that the correct Prescriber information is entered. There can be multiple Prescribers with similar names and you must make sure that the correct Prescriber is identified and selected
- Manual signature of the Prescriber or signature of the Prescriber for EPCS (is an electronic file our system checks for)
- **Reference:** Accepting Prescriptions

16.1 FAXED SCHEDULE III-V PRESCRIPTION

If allowed by your state, faxed prescriptions can be accepted if they have a manual signature (i.e. wet signature) of the Prescriber. A faxed prescriptions with an electronic or typed signature are not valid.

Due to the requirement that faxed prescriptions for controlled substances have been originally wet-signed, controlled substance prescriptions received from electronic fax applications where the signature is affixed within the application (e.g., Doximity, RingCentral) are not valid.

16.2 ORAL SCHEDULE III-V PRESCRIPTION

An oral prescription is acceptable provided that the prescription is promptly reduced to writing by the Pharmacist and contains all information on a written prescription except for the signature of the Prescriber. Verbal prescriptions are to be maintained with other Schedule III-CV prescriptions.

- Some states have more stringent regulations around oral prescriptions. In states where this is the case, the state regulation must be adhered to

Oral prescriptions for **controlled substances (Schedules II, III, IV, and V)** may only be accepted by a Licensed Pharmacist, Graduate Intern, or registered Undergraduate Interns (where allowed).

- **Reference:** Accepting Prescriptions

16.3 REFILLS OF SCHEDULE III-V PRESCRIPTION

Schedule III through IV prescriptions may be refilled if authorized on the prescription. However, under federal law, the prescription may only be refilled five (5) times within six (6) months after the original date of issue, whichever comes first. Afterwards, a new prescription is required.

- State law may be more restrictive

Schedule V prescriptions may only be refilled if authorized on the prescription by the Prescriber.

- Some states impose additional limits on control substance refills

17. BUPRENORPHINE (SUBUTEX OR SUBOXONE) PRESCRIPTIONS - OPIOID ADDICTION TREATMENT MEDICATIONS

Physicians must include their DATA 2000 waiver ID number on prescriptions for opioid addiction treatment medications. The DATA 2000 Waiver ID number is called a NADEAN # and begins with an "X." The Practitioner's DEA registration number and the unique identification number (NADEAN number) must be on the prescription.

- The identification number is not in lieu of the DEA registration number; it is in addition
- If the prescription is telephoned to the Pharmacy, the Pharmacist must have both of these numbers on the prescription record

Note: For buprenorphine/Suboxone prescriptions written for pain, the Prescriber must indicate that the prescription is written for pain treatment.

- For pain prescriptions, no NADEAN number is required

18. LOCKED-IN PATIENTS

- A customer may be restricted to receiving all medication from one Pharmacy location if their use of controlled substance prescriptions is deemed excessive by the Third Party agency. Once a specific Pharmacy is designated as the primary location for a locked-in patient, no other Pharmacy may dispense medication, especially controlled substances for that patient. If a claim is adjudicated to the covering Third Party plan by a Pharmacy that is not designated as the primary location for a locked-in patient, a rejection message would be returned by the agency
    - When such a message of rejection occurs, the non-primary Pharmacy cannot dispense the medication as cash, but must inform the patient to return to their primary location to be serviced
    - Only in limited, emergency situations, such as a medication is needed for treatment of an acute injury and the primary Pharmacy is closed or out of stock, may the locked-in customer be serviced at an alternate location and only if issued an override by the Third Party agency
- To ensure CVS Pharmacy retail locations abide by the restrictions placed on locked-in customers, the following must occur:
    - **For all states other than Massachusetts:** When a Pharmacy receives notification that a customer has been locked into their location, a forced note must be placed into the patient profile (for example: Locked-in Medicaid Patient. CVS: 1234 is Primary Pharmacy. Paying cash is unacceptable.)
    - **For Massachusetts pharmacies only**: All received notification letters must be faxed to the Professional Practice Team at 401-652-0805. Upon receipt, a patient level alert message will be implemented by the corporate office and display at data entry and verification for Pharmacy Teams. The Pharmacy Team must also notify their Field Leader of all received notification letters
        - Responsibilities of Primary Massachusetts Pharmacy. The primary Pharmacy must monitor the prescription utilization pattern of each member, and must exercise sound professional judgment when dispensing all prescription drugs. When the Pharmacist reasonably believes that the member is presenting a prescription that is inappropriate for his or her medical condition, the Pharmacist must contact the Prescriber to verify the authenticity and accuracy of the prescription presented. Primary pharmacies that are found on review to be dispensing drugs in a manner that is inconsistent with professional standards may be subject to administrative action by the MassHealth agency, including the recovery of payments and the imposition of sanctions, in accordance with 130 CMR 450.000: Administrative and Billing Regulations
- When filling controlled substances for a locked-in patient at the primary location, it is strongly recommended that a PMP check occurs to ensure the customer has not filled elsewhere under cash payment

- When a non-primary Pharmacy determines a locked-in patient is trying to obtain a controlled substance at their location and requests to pay cash, the prescription must be refused as this may be an indication of attempted diversion

- If an emergency situation arises for which a non-primary Pharmacy determines the need to service a locked-in patient, the agency must be called to receive an override. In the circumstance that the agency is unavailable and in the professional opinion of the Pharmacist, the member's health or safety would be jeopardized without immediate access to the prescribed drug or if the prescription is for family planning, the prescription may be processed under cash but careful documentation must occur describing the need and circumstances. The agency must then be informed of the fill at the earliest available time
- Pharmacists must review all controlled substance prescriptions for the presence of red flags. If red flags cannot be resolved after due diligence, the prescription must be refused, regardless if the patient is locked-in to your Pharmacy or not

19. PENALTIES FOR VIOLATION OF THIS POLICY/DISPENSING REGULATIONS

It is illegal to knowingly dispense a controlled substance pursuant to an invalid prescription. This includes prescriptions that:

- Are not issued for a legitimate medical purpose by a Practitioner, acting in the usual course of professional practice and a prescription that does not meet the technical requirements (signature, date, DEA number, etc.)
- Violates limitations on oral, facsimile or electronic prescribing
- Appear to be altered, forged or copied

A Pharmacy Colleague who fails to take steps to verify a prescription when there is reason to believe it is not valid and, instead, fills the questionable prescription, can be prosecuted criminally and/or lose his or her professional license in addition to being subject to disciplinary action by CVS Pharmacy up to, and including, termination of employment.

REMEMBER, WHEN BOTH FEDERAL AND STATE REGULATIONS APPLY; THE MORE STRINGENT REQUIREMENTS MUST BE FOLLOWED.

DEFINITIONS

1. **CVS Health®:** CVS Health Corporation and each of its subsidiaries and affiliates.
2. **CVS Pharmacy®:** CVS Pharmacy, Inc., and each of its retail–pharmacy and distribution center subsidiaries and affiliates.
3. **CVS Retail:** Operations of CVS Health to include the retail pharmacy and retail front store businesses.
4. **CVS Caremark®:** Caremark Rx, L.L.C. and each of its pharmacy benefit management subsidiaries and affiliates, including Caremark, L.L.C.
5. **Colleague**: Any full-time, part-time, temporary, or casual employee of CVS Health® and each of its subsidiaries and affiliates, along with paid interns and externs employed by CVS Health® and each of its subsidiaries and affiliates.

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ROPP-047561	Federal Regulations and CVS Pharmacy Guidelines for Controlled Substances

REVIEW AND REVISION HISTORY

Date	Revision No.	Reason for Change	Sections Affected
10/01/14	1.00	New Policy and Procedure	all
10/15/14	2.00	Update Policy and Procedure	Perpetual and Monthly Inventory Requirements and Documentation
12/18/14	3.00	Update Policy and Procedure	Dispensing Controlled Substances
06/15/15	4.00	Update Policy and Procedure	Oral CII Prescription and Oral CIII-CV Prescription
10/28/15	5.00	Update Policy and Procedure	All
01/12/16	6.00	Update Policy and Procedure	All
07/11/16	7.00	Annual Review; no changes	N/A
09/27/16	8.00	Updated Policy and Procedure	All
12/28/16	9.00	Updated Policy and Proceure	Section 15.3, Update RxNet Links
05/12/17	10.00	Update policy and procedure	All
05/02/18	11.00	Annual Review	Header, Footer, or Review and Revision History, Record Keeping, DEA 222 Form Information, Receiving Schedule II Controlled Substances, Ordering Schedule III – V Controlled Substances, Storage and Security of Controlled Substances, DEA Required Inventories and Documentation, Perpetual and Monthly Inventory Requirements and Documentation, Lost in Transit (In-Transit Losses), Contacting Prescribers for Clarification, Faxed Schedule II Prescription, Oral Schedule II Prescription, Faxed Schedule III-V Prescription, Oral Schedule III-V Prescription, Buprenorphine (Subutex Or Suboxone) Prescriptions - Opioid Addiction Treatment Medications, Locked-In Patients

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02/06/19	12.00	Update Policy and Procedure	Footer, Review and Revision History, Definitions, Section 14